DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 22, 2000

Ms. Margaret Gilhooley
Professor of Law
Seton Hall University
One Newark Center
Newark, New Jersey 07102

Dear Ms. Gilhooley:

Thank you for your thoughtful letter of January 18, urging the Food and Drug Administration (FDA) to reopen rulemaking on dietary supplement structure and function claims, or issue a revised statement about our position on morning sickness as a claim.

In the final rule, FDA announced that it would not treat as diseases common conditions associated with natural states or processes that do not cause significant or permanent harm and that claims about beneficial effects on such conditions would not be treated as disease claims. FDA stated that claims about common, mild conditions related to pregnancy, such as morning sickness and leg edema, would be considered structure/function claims.

After we published the final rule, we received additional comments such as yours that raised concerns about the safety of dietary supplement use during pregnancy. As a result, on February 9, we issued a statement that advised dietary supplement manufacturers not to make any claims related to pregnancy on their products until additional guidance is issued. The Agency has placed on public display a Federal Register notice announcing that it is holding a public meeting on March 30, in the Crystal Ballroom of the Gaithersburg Hilton to discuss safety issues associated with dietary supplement use during pregnancy. You are certainly encouraged to attend this public meeting. If you wish to speak during the meeting, you will need to file a notice of participation by March 17. The notice of participation form, which can be submitted electronically, will be available at the following web site: http://www.fda.gov/cder/calendar/meeting/pregsup2000/default.htm. This site will also contain a copy of the Federal Register notice, questions to be addressed, and other relevant information.

Once again, thank you for your comments and concerns.

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

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